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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,950

05/19/2006

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EXAMINER

ZALASKY, KATHERINE M

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

08/17/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No. 10/553,950	Applicant(s) UCHI ET AL.	
	Examiner KATHERINE ZALASKY	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 13 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 13 and 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20100528</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Status

1. **Claims 1, 13 and 15-20**, as amended 21 May 2010, are currently pending. **Claims 2-12 and 14** are cancelled.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. **Claims 1, 13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukasawa et al. (EP 0306613).**

Regarding **claim 1**, Fukasawa et al. discloses a hollow fiber membrane type fluid treatment device (pg 3, L19-22) comprising:

- at least a body portion of tubular housing (15) containing a hollow fiber membrane bundle (17)
- a housing head portion (29) which is connected with one end of the housing body portion and has a resin layer (19) where the hollow fiber membrane bundle is fixed by using a resin composition (pg 6/L16-25) and a connection port (27) which serves as a treatment liquid inlet
- a housing head portion (30) which is connected with the other end of the housing body portion and has a resin layer where the hollow fiber membrane bundle is fixed by using a resin composition (pg 6/L16-25) and a connection port which serves as a treatment liquid outlet (28)
- header caps (20, 21) attached to the housing head portions and having respective treatment target liquid connection ports (23, 25)

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- an inner surface of a body portion of the tubular housing at the side of a treatment liquid inlet comprises a body straight portion (Figures 3-4, straight portions on the inner surface, near to ports 27 & 28) and an end tapered portion which increases in diameter toward the end face of the housing body portion (Figure 3)
- the hollow fiber membranes are arranged so that a distance between the hollow fiber membranes is gradually increased toward the end face on the treatment liquid inlet side along a taper of a tapered portion of the inner surface of the housing body portion (Figure 3 & pg 5/L22-33)
- opening ends of the hollow fiber membrane bundle being fixed to an inside of the housing by the resin layers and the opening ends of the hollow fiber membrane bundle facing the respective treatment target liquid connection ports (pg 6/L16-25, Figure 3, ports 23, 25)
- the treatment liquid inlet and treatment liquid outlet being provided at a circumference of the hollow fiber membrane bundle (Figure 3, ports 27, 28)

While the reference does not explicitly disclose the device wherein an angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is greater than 0° and smaller than an angle defined by $\tan^{-1} \{(1/2) \cdot (d1-d4)/L4\}$. As the packing density and thus the efficiency of treatment fluid exchange are variables that can be modified, among others, by adjusting said angle, the precise angle would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made (see pg 5, L25-28). As such, without showing unexpected results, the claimed angle cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the angle in the

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apparatus of modified Fukasawa to obtain the desired packing density and efficiency (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 223).

Regarding limitations recited in **claim 1** which are directed to a manner of operating disclosed apparatus (“wherein a liquid to be treated flows within the hollow fiber membranes and a treatment liquid flows outside of the hollow fiber membranes”), it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

Regarding **claim 13**, Fukasawa et al. discloses all of the claim limitations as set forth above. Additionally, the reference discloses the device wherein the tapered portion comprises:

- a first tapered portion located on the body portion side (Figure 3, tapered portions by passages 29 & 30)
- a second tapered portion located on the treatment liquid inlet side (Figure 3, tapered portions by ports, 27 & 28)
- the angle of the first taper angle is smaller than the angle of the second taper angle (Figure 3, pg 4/L57 – pg 5/L2)

Regarding **claim 15**, Fukasawa et al. discloses all of the claim limitations as set forth above, but does not explicitly disclose the device wherein the angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is

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greater than 0.58° and smaller than an angle defined by $\tan^{-1} \{(1/2) \cdot (d1-d4)/L4\}$. As the packing density and thus the efficiency of treatment fluid exchange are variables that can be modified, among others, by adjusting said angle, the precise angle would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made (see pg 5, L25-28). As such, without showing unexpected results, the claimed angle cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the angle in the apparatus of modified Fukasawa to obtain the desired packing density and efficiency (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 223).

Regarding **claim 16**, Fukasawa et al. discloses all of the claim limitations as set forth above. While the reference does not explicitly disclose the ratio of the length of the body straight portion to the total length of the end tapered portion being between 0.7 to 20 and the ratio of the inner diameter of the end tapered portion on the end face side to the inner diameter of the body straight portion being more than 1 and not more than 3, since the instant specification is silent to unexpected results, it would have been obvious to one of ordinary skill in the art to change the lengths of the tapered and straight body portions as well as the diameters, since such a modification would have involved a mere change in the size (or dimension) of a component. A change in size (or dimension) is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device, and the device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device, *Gardner v. TEC*

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Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Regarding **claim 17**, modified Fukasawa discloses all of the claim limitations as set forth above. Regarding limitations recited in **claim 17** which are directed to a manner of operating disclosed device (e.g. “a urea clearance of 191 to 200 ml/min”), it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

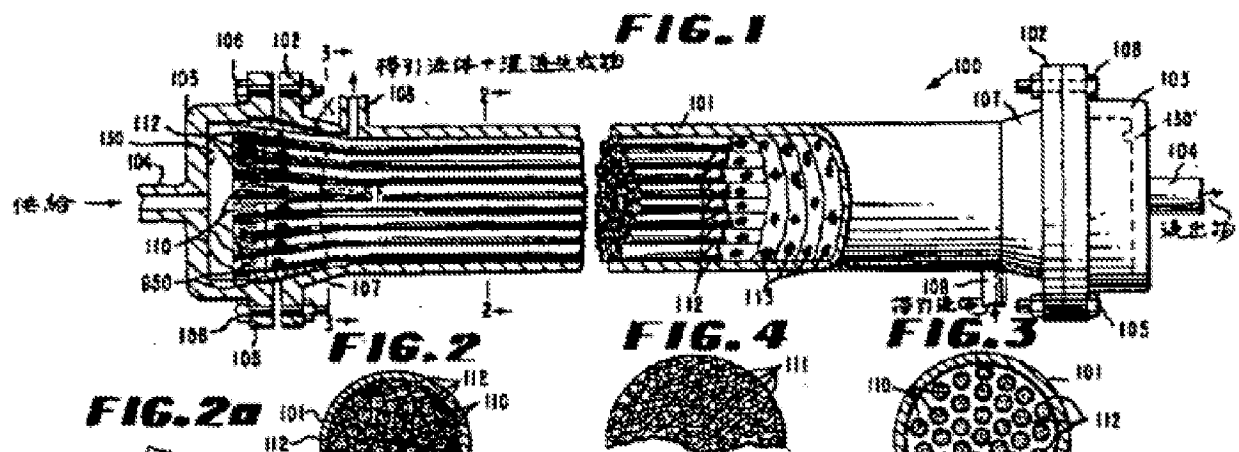
4. **Claim 1, 15-17 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 44-5526.

Regarding **claim 1**, JP 44-5526 discloses a hollow fiber membrane type fluid treatment device (Figure 1) comprising:

- at least a body portion of tubular housing containing a hollow fiber membrane bundle (Figure 1, housing 101, fibers 110)
- a housing head portion (102) which is connected with one end of the housing body portion and a connection port (108) which serves as a treatment liquid inlet
- a housing head portion (102) which is connected with the other end of the housing body portion and a connection port which serves as a treatment liquid outlet (108)
- header caps (103) attached to the housing head portions and having respective treatment target liquid connection ports (104)

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- an inner surface of a body portion of the tubular housing at the side of a treatment liquid inlet comprises a body straight portion (central portion of housing 101) and an end tapered portion which increases in diameter toward the end face of the housing body portion (tapered portion on ends, 107)
- the hollow fiber membranes are arranged so that a distance between the hollow fiber membranes is gradually increased toward the end face on the treatment liquid inlet side along a taper of a tapered portion of the inner surface of the housing body portion (Figure 1)
- opening ends of the hollow fiber membrane bundle being fixed to an inside of the housing by the resin layers and the opening ends of the hollow fiber membrane bundle facing the respective treatment target liquid connection ports (Figure 1, ports 104)
- the treatment liquid inlet and treatment liquid outlet being provided at a circumference of the hollow fiber membrane bundle (Figure 1, ports 108)



While the reference does not explicitly show a resin layer where the hollow fiber membrane bundle is fixed by using a resin composition, it is very well known in the art to use a resin plug near the header portion of a hollow fiber membrane module (as evidenced by

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Fukasawa et al., EP 0306613, pg 6/L16-25). Therefore, it would have been obvious to one having ordinary skill in the art to use a resin material to fix the hollow fiber membranes in place near the headers since doing so amounts to nothing more than the use of a widely known and utilized technique for constructing hollow fiber membrane modules.

While the reference does not explicitly disclose the device wherein an angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is greater than 0° and smaller than an angle defined by $\tan^{-1} \{(1/2) \cdot (d1-d4)/L4\}$. As the packing density and thus the efficiency of treatment fluid exchange are variables that can be modified, among others, by adjusting said angle, the precise angle would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made (see Fukasawa et al. (EP 0306613), pg 5, L25-28). As such, without showing unexpected results, the claimed angle cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the angle in the apparatus of modified Fukasawa to obtain the desired packing density and efficiency (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 223).

Regarding limitations recited in **claim 1** which are directed to a manner of operating disclosed apparatus ("wherein a liquid to be treated flows within the hollow fiber membranes and a treatment liquid flows outside of the hollow fiber membranes"), it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have

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patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

Regarding **claim 15**, JP 44-5526 discloses all of the claim limitations as set forth above, but does not explicitly disclose the device wherein the angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is greater than 0.58° and smaller than an angle defined by $\tan^{-1} \{(1/2) \cdot (d1-d4)/L4\}$. As the packing density and thus the efficiency of treatment fluid exchange are variables that can be modified, among others, by adjusting said angle, the precise angle would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made (see Fukasawa et al. (EP 0306613), pg 5, L25-28). As such, without showing unexpected results, the claimed angle cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the angle in the apparatus of modified Fukasawa to obtain the desired packing density and efficiency (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 223).

Regarding **claim 16**, JP 44-5526 discloses all of the claim limitations as set forth above. While the reference does not explicitly disclose the ratio of the length of the body straight portion to the total length of the end tapered portion being between 0.7 to 20 and the ratio of the inner diameter of the end tapered portion on the end face side to the inner diameter of the body straight portion being more than 1 and not more than 3, since the instant specification is silent to unexpected results, it would have been obvious to one of ordinary skill in the art to change the lengths of the tapered and straight body portions as well as the diameters, since such a

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modification would have involved a mere change in the size (or dimension) of a component. A change in size (or dimension) is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device, and the device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device, *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Regarding **claim 17**, JP 44-5526 discloses all of the claim limitations as set forth above. Regarding limitations recited in **claim 17** which are directed to a manner of operating disclosed device (e.g. "a urea clearance of 191 to 200 ml/min"), it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states "Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim."

Regarding **claim 20**, JP 44-5526 discloses all of the claim limitations as set forth above. Additionally, the reference discloses the hollow fiber membrane type fluid treatment device wherein the body straight portion extends from a central portion of the housing body portion (Figure 1, central portion of housing 101).

5. **Claims 18-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukasawa et al. (EP 0306613), as applied to **claim 1** above, and further in view of Kanno et al. (US 4,201,673).

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Regarding **claims 18-19**, Fukasawa et al. discloses all of the claim limitations as set forth above. The reference does not explicitly disclose the device comprising baffle plates provided at positions corresponding to the treatment liquid inlet and the treatment liquid outlet of the tubular housing and interspatially from the inner circumference of the tubular housing over the entire inner circumference at a curvature almost along the inner circumference. Further, the reference does not disclose the device wherein the baffle plate gradually increases in diameter toward the end face of the housing.

Kanno et al. discloses a dialyzer with hollow fiber membranes (abstract) which contains a baffle plate (annular rib 15) which increases in diameter toward the end of the housing (see Figures 2 & 3). Kanno et al. teaches that a baffle plate may help avoid channeling and may improve efficiency by allowing dialysate to flow over the outermost hollow fibers (C1/L45-60).

Fukasawa et al. and Kanno et al. are analogous because both references are directed to hollow fiber membrane modules.

It would have been obvious to one having ordinary skill in the art at the time of the invention to add a baffle plate to the module of Fukasawa et al, as taught by Kanno et al., since doing so may help avoid channeling, thereby improving the efficiency of the device.

Response to Arguments

6. Applicant's arguments filed 21 May 2010 have been fully considered but they are not persuasive.

7. The Applicant has argued that Fukasawa does not disclose the details of amended claim 1 because the optimization of the angles in the reference, as provided by the rejection above, is improper. The Applicant states that they have significant results by using an angle as defined by the claim, thus the optimization would be non-obvious. However, the results of presented in the instant specification do not support the full range of the claim limitation and do not support

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that the improvement was unexpected. The comparative examples in the instant specification are hollow fiber membrane modules having no angle at all; there is not a single comparative example presented that shows the criticality of the particular range of angles claimed. The references applied all have angled sides, the angle may be optimized based on the properties discussed in the rejection. Where is the evidence which supports that the results of the instant invention are unexpected? Has the problem of the fluid taking a short path through the module been an unsolved problem facing the area of art? Where is the evidence which supports that the particular range of angles claimed is significant? The current evidence presented in the specification merely shows that a module with angled ends has better results/separation properties than a module which is completely straight.

8. While the rejection of **claim 14** was not previously made with JP 44-5526, the new combination presented by **claim 20**, **claim 16** and **claim 1** forced the Examiner to consider the reference again.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE ZALASKY whose telephone number is (571) 270-7064. The examiner can normally be reached on 7:30am - 6:00pm Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1797

/KZ/
11 August 2010